

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	PEL	NON-PEL
Scope and Application	<p>(1) This section applies to occupational exposures to flavorings containing diacetyl in:</p> <p>(i) Industries and establishments that manufacture flavorings; and</p> <p>(ii) Industries and establishments that manufacture food products.</p> <p>(2) This section applies to an establishment, covered under paragraph (1), where an employee is diagnosed with a flavoring-related lung or skin disease regardless of whether the employer has objective data or monitoring data as described in paragraph (3).</p> <p>(3) This section does not apply to establishments for which the employer has objective data or monitoring data demonstrating that:</p> <p>All employee exposures to a flavoring containing diacetyl cannot exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour time weighted average [TWA]) or a 15-minute short term exposure of 0.2 ppm under any expected conditions of use.</p>	<p>(1) This section applies to occupational exposures to flavorings containing diacetyl in:</p> <p>(i) Industries and establishments that manufacture flavorings; and</p> <p>(ii) Industries and establishments that manufacture food products.</p> <p>(2) This section applies to an establishment, covered under paragraph (1), where an employee is diagnosed with a flavoring-related lung or skin disease regardless of whether the employer has objective data or monitoring data as described in paragraph (3).</p> <p>(3) This section does not apply to establishments for which the employer has objective data or monitoring data demonstrating that:</p> <p>All employee exposures to a flavoring containing diacetyl cannot exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour time weighted average [TWA]) or a 15-minute short term exposure of 0.2 ppm under any expected conditions of use.</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Definitions		
<p><i>Action Level</i> means a concentration of airborne diacetyl that is half of the PEL (or possibly another value below the PEL).</p> <p><i>Assistant Secretary</i> means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.</p> <p><i>Diacetyl</i> (CAS # 431-03-8) means an organic compound with the SMILES chemical formula <chem>CC(=O)C(C)=O</chem> that has a molecular weight of approximately 86.09 gm/mole.</p> <p><i>Emergency</i> means any occurrence that results, or is likely to result, in an uncontrolled release of flavorings containing diacetyl. When an incidental release of flavorings containing diacetyl can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.</p> <p><i>Employee exposure</i> means the exposure to diacetyl or flavorings containing diacetyl that would occur when the employee is not using a respirator.</p> <p><i>Flavoring-related lung disease</i> means obstructive lung disease in an employee exposed to flavorings containing diacetyl. For these purposes, obstructive lung disease is defined as a ratio of the forced expiratory volume₁ (FEV₁) to the forced vital capacity (FVC) that is below the lower limit of normal, using National Health and</p>	<p><i>Assistant Secretary</i> means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.</p> <p><i>Diacetyl</i> (CAS # 431-03-8), also called butanedione or 2,3-butanedione, means an organic compound with the SMILES chemical formula <chem>CC(=O)C(C)=O</chem> that has a molecular weight of approximately 86.09 gm/mole.</p> <p><i>Emergency</i> means any occurrence that results, or is likely to result, in an uncontrolled release of flavorings containing diacetyl. When an incidental release of flavorings containing diacetyl can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.</p> <p><i>Employee exposure</i> means the exposure to diacetyl or flavorings containing diacetyl that would occur when the employee is not using a respirator.</p> <p><i>Flavoring-related lung disease</i> means obstructive lung disease in an employee exposed to flavorings containing diacetyl. For these purposes, obstructive lung disease is defined as a ratio of the forced expiratory volume₁ (FEV₁) to the forced vital capacity (FVC) that is below the lower limit of normal, using National Health and Nutrition Examination Survey (NHANES) reference values, or a FEV₁ that is more than 15% below the</p>	

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>Nutrition Examination Survey (NHANES) reference values, or a FEV₁ that is more than 15% below the employee's personal best FEV₁.</p> <p><i>Flavoring-related skin disease</i> means any dermal irritation or pathology that the PLHCP believes is related to exposure to flavorings containing diacetyl.</p> <p><i>Flavorings containing diacetyl</i> means substances, added to impart or help impart a taste or aroma in food, that contain diacetyl. Pure diacetyl and fall within this definition, when used to impart or help impart a taste or aroma in food.</p> <p><i>High-efficiency particulate air (HEPA) filter</i> means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.</p> <p><i>Industries and establishments that manufacture flavorings</i> means facilities that make flavorings for distribution and wholesale, but does not include restaurant or cafeteria kitchens where cooks make flavorings in the course of preparing food for customers.</p> <p><i>Industries and establishments that manufacture foods</i> means facilities that make food, but does not include restaurants, cafeterias, or kitchens in institutions such as hospitals or schools.</p>	<p>employee's personal best FEV₁.</p> <p><i>Flavoring-related skin disease</i> means any dermal irritation or pathology that the PLHCP believes is related to exposure to flavorings containing diacetyl.</p> <p><i>Flavorings containing diacetyl</i> means substances, added to impart or help impart a taste or aroma in food, that contain diacetyl. Pure diacetyl fall within this definition, when used to impart or help impart a taste or aroma in food.</p> <p><i>High-efficiency particulate air (HEPA) filter</i> means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.</p> <p><i>Industries and establishments that manufacture flavorings</i> means facilities that make flavorings for distribution and wholesale, but does not include restaurant or cafeteria kitchens where cooks make flavorings in the course of preparing food for customers.</p> <p><i>Industries and establishments that manufacture foods</i> means facilities that make food, but does not include restaurants, cafeterias, or kitchens in institutions such as hospitals or schools.</p> <p><i>Mixing</i> means blending the components of a mixture together. Mixing also refers to compounding, formulating.</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p><i>Objective data</i> means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to flavorings containing diacetyl and associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.</p> <p><i>Physician or other licensed health care professional (PLHCP)</i> is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by the medical surveillance provisions of this section.</p>	<p><i>Mixing area</i> means an area in the plant where flavorings containing diacetyl are mixed.</p> <p><i>Objective data</i> means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to flavorings containing diacetyl and associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.</p> <p><i>Produce</i> means pour, weigh, bag, transfer, spray, or perform other operations involved in the manufacture of flavorings or foods.</p> <p><i>Production room</i> means a room where workers pour, weigh, bag, transfer, or perform other operations with flavoring containing diacetyl as part of the manufacture of flavorings or foods.</p> <p><i>Solid barrier</i> means a structurally sound wall or enclosure.</p> <p><i>Tank</i> means any vessel used for mixing or holding flavorings containing diacetyl.</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>Permissible Exposure Limit (PEL)</p>	<p>(1) The employer shall ensure that no employee is exposed to an airborne concentration of diacetyl in excess of the PEL of (0.05, 0.1, 0.5, or 1.0) ppm 8-hour TWA or a STEL of (0.2, 0.5, 2.0, or 4.0) ppm (15 minutes);</p>	(N/A)
<p>Exposure assessment</p>	<p>(1) <u>General</u>. Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure and 15 minute short-term exposure level for each employee exposed to flavorings containing diacetyl.</p> <p>(2) <u>Scheduled monitoring</u>. (i) The employer shall perform initial monitoring to determine the 8-hour TWA and 15 minute short-term exposure level for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest exposures;</p> <p>(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring;</p> <p>(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform</p>	<p>(1) <u>Initial assessment</u>. Each employer who has an establishment covered by this section shall perform an initial assessment to determine the airborne concentrations of diacetyl contained in flavorings, to which employees may be exposed. This initial assessment shall consist of:</p> <p>(i) Representative 8-hour TWA and 15-minute short-term concentrations determined on the basis of one or more personal breathing zone air samples representing employee exposure for each shift and for each job classification in each work area; or</p> <p>(ii) Engineering studies or other objective data indicating the levels of flavorings containing diacetyl to which employees are exposed.</p> <p>(2) <u>Additional assessment</u>. Employers shall conduct additional exposure assessment whenever:</p> <p>(i) Changes in production process, raw materials, equipment, personnel, work practices, or control methods may increase employee exposure; or</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>periodic monitoring at least every six months;</p> <p>(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months;</p> <p>(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring;</p> <p>(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures or when the employer has any reason to believe that new or additional exposures have occurred.</p> <p>(3) <u>Employee notification of determination results.</u> (i) Where the exposure determination indicates that employee exposure exceeds the PEL, within 15 working days of receipt of the results, the employer shall either post the results in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing of the results.</p> <p>(ii) Whenever the exposure determination indicates that employee exposure is above the PEL, the employer shall</p>	<p>(ii) An employee has been diagnosed with flavoring-related lung or skin disease.</p> <p>(3) Where the employer can establish and document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.</p> <p>(4) Where an employer relies upon objective data or performs representative sampling to conduct an exposure assessment, the employer shall assess the exposure of the employee(s) expected to have the highest exposure.</p> <p>(5) <u>Employee notification of determination results.</u></p> <p>(i) Within 15 working days of the completion of the exposure assessment, the employer shall either post the results of the assessment in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing; and</p> <p>(ii) The employer shall describe in the written notification any corrective action being taken to reduce employee exposure.</p> <p>(6) <u>Accuracy of measurement.</u> (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure diacetyl to within an</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.</p>	<p>accuracy of plus or minus 25 percent (+/- 25%), at a statistical confidence level of 95 percent for airborne concentrations.</p>
<p>(4) <u>Accuracy of measurement.</u> Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure diacetyl within an accuracy of plus or minus 25 percent (+/- 25%), at a statistical confidence level of 95 percent for airborne concentrations.</p>	<p>(ii) Samples shall be collected and analyzed according to the procedures presented in Mandatory Appendix, or according to an equivalent method.</p>
<p>(ii) Samples shall be collected and analyzed according to the procedures presented in Mandatory Appendix, or according to an equivalent method.</p>	<p>(7) <u>Observation of monitoring.</u> (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to flavorings containing diacetyl;</p>
<p>(5) <u>Observation of monitoring.</u> (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure.</p>	<p>(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment with all other applicable safety and health procedures; and</p>
<p>(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.</p>	

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Exposure control plan	N/A	<p>(1) Employers covered under the scope of this section shall prepare a written exposure control plan that, at minimum:</p> <ul style="list-style-type: none"> (i) Describes the specific work operations and sources of emission, identified through exposure assessment (as required under this section), where exposure and potential exposure to flavorings containing diacetyl occurs; (ii) Identifies engineering controls and work practices in use; (iii) Identifies regulated areas and the methods to used to demarcate them; (iv) Documents the effectiveness of engineering controls and work practices in use; (v) Establishes a leak prevention, detection, and repair procedure; (vi) Describes engineering controls and work practices that are planned and the timeline for implementation; (vii) Identifies required personal protective equipment, including respirators, and specifies work areas in which the use of such equipment is required in accordance with 29 CFR 1910.132, 133, and 138;
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

		<p>(viii) Provides an employee exposure monitoring program, as required under this section, that includes criteria for selecting employees and tasks to be monitored, and methods for collecting and analyzing samples for diacetyl contained in the specific flavoring formulation;</p> <p>(ix) Identifies procedures and prohibitions for cleaning areas where flavorings containing diacetyl are used, as required under the housekeeping provisions of this section; and</p> <p>(x) Describes emergency procedures.</p> <p>(2) Employers shall update the written control plan whenever changes in production process, raw materials, equipment, personnel, work practices, or control methods may increase employee exposure.</p>
Regulated Areas	<p>(1) <u>Establishment</u>. The employer shall establish a regulated area wherever an employee's exposure is, or can reasonably be expected to be, in excess of the PEL.</p> <p>(2) <u>Demarcation</u>. The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees of the boundaries of the regulated area.</p> <p>(3) <u>Access</u>. The employer shall limit access to regulated areas to:</p>	<p>(1) <u>Establishment</u>. The employer shall establish a regulated area:</p> <p>(i) when employees pour, weigh, mix, spray, transfer, or bag flavorings containing diacetyl;</p> <p>(ii) when employees engage in processes that generate exposures similar to those that occur during the pouring, weighing, mixing, spraying, transfer, or bagging of flavorings containing diacetyl; and</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(i) Persons authorized by the employer and required by work duties to be present in the regulated area;</p> <p>(ii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; or</p> <p>(iii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.</p>	<p>(iii) during emergency cleanup.</p> <p>(2) <u>Demarcation</u>. The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes the area where exposure occurs and alerts employees of the boundaries of the regulated area.</p> <p>(3) <u>Access</u>. The employer shall limit access to regulated areas to:</p> <p>(i) Persons authorized by the employer and required by work duties to be present in the regulated area;</p> <p>(ii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area; and</p> <p>(iii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under the exposure assessment provisions of this section.</p>
<p>Methods of compliance</p>	<p>(1) <u>Engineering and work practice controls</u>.</p> <p>(i) Except as permitted in paragraph (1)(ii) of provisions describing methods of compliance, the employer shall use engineering and work practice controls to reduce and maintain employee exposure at or below the PEL unless the employer can demonstrate that such controls are not</p>	<p>(1) <u>Engineering and work practice controls</u>. In areas where flavorings containing diacetyl are mixed, produced, or added to food, employers shall:</p> <p>(i) Isolate areas in which flavorings containing diacetyl are mixed, produced, or added to food, using solid barriers and providing ventilation sufficient to maintain a</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure at or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the respiratory protection provisions of this section.</p> <p>(ii) Where the employer can demonstrate that a process or task does not result in any employee exposure above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.</p>	<p>negative pressure of 0.04 inches water gauge ("w.g.") plus or minus 0.02 "w.g. relative to the areas adjacent to the mixing or production room. This ventilation system shall exhaust outside the building or to an area where no workers are present;</p> <p>(ii) Ventilate mixing operations with local exhaust hoods that provide at minimum a capture velocity of 100 feet per minute and ensure the use of local exhaust hoods during all mixing and compounding operations;</p> <p>(iii) Enclose mixing and storage tanks and equip openings with an airtight lid or hatch. Mixing and storage tanks shall be equipped with local exhaust ventilation that maintains the interior of the tank at a negative pressure with respect to the mixing or production room even when the access lid or hatch is open;</p> <p>(iv) Maintain temperature of mixing and storage tank contents as low as the production process will allow;</p> <p>(v) Clean mixing and storage tanks and other process equipment with water or other cleaning agent at ambient temperature.</p> <p>(2) Employers shall install and ensure the use of laboratory hoods or equally effective local exhaust ventilation hood that provides a minimum face velocity of 100 feet per minute for any research and development or quality control activities with exposure or potential</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

		exposure to flavorings containing diacetyl.
Respiratory Protection	<p>(1) <u>General</u>. The employer shall provide respiratory protection for employees during:</p> <p>(i) Periods necessary to install or implement feasible engineering and work practice controls;</p> <p>(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;</p> <p>(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;</p> <p>(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or</p> <p>(v) Emergencies.</p> <p>(2) <u>Respiratory protection program</u>. Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.</p>	<p>(1) For every employee covered under paragraph (2) of the respiratory protection provisions, employers shall, at a minimum, provide a full-face air purifying respirator equipped with combination organic vapor and particulate filters.</p> <p>(2) Employers shall provide respiratory protection in accordance with 29 CFR 1910.134 (except paragraph D) of 29 CFR 1910.134):</p> <p>(i) When employees pour, weigh, mix, spray, transfer or bag flavorings containing diacetyl;</p> <p>(ii) When employees engage in processes that generate exposures similar to those that occur during the pouring, weighing, mixing, spraying, transferring, or bagging of flavorings containing diacetyl; and</p> <p>(iii) When employees perform work operations such as maintenance, sanitation, and repair activities, for which engineering and work practice controls are not feasible;</p> <p>(iv) During emergency cleanup; and</p> <p>(v) During periods necessary to install or implement feasible engineering and work-practice controls.</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Protective work clothing and equipment	<p>(1) Provision and use. Where a hazard is present or is likely to be present from skin or eye contact with flavorings containing diacetyl, the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.</p> <p>(2) Removal and storage. (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with flavorings containing diacetyl at the end of the work shift or at the completion of their tasks involving exposure, whichever comes first.</p> <p>(ii) The employer shall ensure that no employee removes contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.</p> <p>(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.</p> <p>(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR</p>	(The Agency anticipates that provisions relating to protective work clothing and equipment will be largely the same in PEL and non-PEL proposals)
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>1910.1200.</p> <p>(3) <u>Cleaning and replacement.</u> (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.</p> <p>(ii) The employer shall prohibit the removal of flavorings containing diacetyl from protective clothing and equipment by blowing, shaking, or any other means that disperses flavorings containing diacetyl into the air or onto an employee's body.</p> <p>(iii) The employer shall inform any person who launders or cleans contaminated protective clothing or equipment of the potentially harmful effects of exposure to flavorings containing diacetyl, and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with and effectively prevents the release of flavorings containing diacetyl in excess of the PEL.</p>	
<p>Hygiene areas and practices</p>	<p>(1) General. Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with flavorings containing diacetyl occurs, the employer shall provide washing facilities in conformance with 29 CFR 1910.141. Eating and drinking areas provided by the employer shall also be in conformance with §1910.141.</p>	<p>(The Agency anticipates that provisions relating to hygiene areas and practices will be the same in PEL and non-PEL proposals)</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(2) <u>Change rooms.</u> The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.</p> <p>(3) <u>Washing facilities.</u> (i) The employer shall provide readily accessible washing facilities capable of removing flavorings containing diacetyl from the skin, and shall ensure that affected employees use these facilities when necessary.</p> <p>(ii) The employer shall ensure that employees who have skin contact with flavorings containing diacetyl wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.</p> <p>(4) <u>Eating, drinking, and smoking areas.</u> (i) Whenever the employer allows employees to consume food or beverages at a worksite where flavorings containing diacetyl are present, the employer shall ensure that eating drinking, and smoking areas and surfaces are maintained as free as practicable of flavorings containing diacetyl.</p> <p>(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface flavorings containing diacetyl have been removed from the clothing and equipment by methods that do not disperse these</p>	
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	chemicals into the air or onto an employee's body. (5) <u>Prohibited activities</u> . The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, or in areas where skin or eye contact with flavorings containing diacetyl occurs; or carry the products associated with these activities, or store such products in these areas.	
Hazard Communication	<p>(1) In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall communicate with and train employees with sufficient frequency to ensure by that each employee can demonstrate knowledge of at least the following:</p> <p>(A) The contents of this section;</p> <p>(B) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.</p>	<p>(1) In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall communicate with and train employees with sufficient frequency to ensure by that each employee can demonstrate knowledge of at least the following:</p> <p>(A) The contents of this section;</p> <p>(B) An explanation of the employer's Exposure Control Plan and the means by which the employee can obtain a copy of the written plan.</p> <p>(C) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.</p>
Medical Surveillance	<p>(1) <u>General</u>. (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:</p> <p>(A) Who are or may be occupationally exposed to</p>	<p>(1) <u>General</u>. (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:</p> <p>(A) Working in areas where flavorings containing</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>flavorings containing diacetyl at or above the action level for 30 or more days a year;</p> <p>(B) Experiencing signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl;</p> <p>(C) Exposed in an emergency to flavorings containing diacetyl; or</p> <p>(D) Working in an area or engaged in a process that is the same or similar to that of an employee who has been diagnosed with flavoring-related disease.</p> <p>(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.</p> <p>(2) <u>Frequency</u>. The employer shall provide a medical examination:</p> <p>(i) Before the time of initial assignment, unless the employee has received a medical examination related to flavorings containing diacetyl, that meets the requirements of this section within the last six months;</p> <p>(ii) Every six months, or more frequently when deemed necessary by the PLHCP;</p> <p>(iii) Whenever an employee shows signs or symptoms associated with exposure to flavorings containing</p>	<p>diacetyl or acetoin are mixed, produced, or added to foods;</p> <p>(B) Working in maintenance, sanitation, quality control, or laboratory environments where flavorings containing diacetyl are present;</p> <p>(C) Experiencing signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl;</p> <p>(D) Exposed in an emergency to flavorings containing diacetyl or</p> <p>(E) Working in an area or engaged in a process that is the same or similar to that of an employee who has been diagnosed with flavoring-related disease.</p> <p>(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.</p> <p>(2) <u>Frequency</u>. The employer shall provide a medical examination:</p> <p>(i) Before the time of initial assignment, unless the employee has received a medical examination related to flavorings containing diacetyl, that meets the requirements of this section within the last six months;</p> <p>(ii) Every six months, or more frequently when deemed</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>diacetyl;</p> <p>(iv) Within 30 days after exposure during an emergency which results in an uncontrolled release of flavorings containing diacetyl; or</p> <p>(v) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (4) was less than six months prior to the date of termination.</p> <p>(vi) Whenever an employee who works in a similar area or process is diagnosed with flavoring-related lung disease.</p> <p>(3) <u>Content of examination.</u> A medical examination consists of, at a minimum:</p> <p>(i) A medical and work history, with emphasis on past, present and potential exposure to flavorings containing diacetyl;</p> <p>(ii) A physical examination with emphasis on the respiratory system, eyes and the integumentary system;</p> <p>(iii) Completion of the respiratory questionnaire in Appendix or other equivalent questionnaire;</p> <p>(iv) Spirometry administered by individuals who have completed a training course in spirometry that is</p>	<p>necessary by the PLHCP;</p> <p>(iii) Whenever an employee shows signs or symptoms associated with exposure to flavorings containing diacetyl;</p> <p>(iv) Within 30 days after exposure during an emergency which results in an uncontrolled release of flavorings containing diacetyl; or</p> <p>(v) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (4) was less than six months prior to the date of termination.</p> <p>(vi) For employees covered under (1)(i)(E) of the medical surveillance provisions, within 30 days after an employee who works in a similar area or process is diagnosed with flavoring-related lung disease.</p> <p>(3) <u>Termination.</u> Medical surveillance may be reduced in frequency or terminated for employees in a particular job or location if:</p> <p>(i) Using the representative sampling procedures [using the OSHA/SLTC method found in Appendix], an employer demonstrates that employees working in the particular job or location have no measurable exposure to diacetyl or acetoin; and</p> <p>(ii) Three consecutive rounds of medical surveillance at</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>certified by NIOSH;</p> <p>(vi) any other additional tests deemed appropriate by the PLHCP; and</p>	<p>6-month intervals demonstrate no change in spirometry readings and the absence of flavoring-related skin disease among all employees working in the particular job or location.</p>
	<p>(v) At a minimum, spirometry shall include measurement of forced vital capacity (FVC) and forced expiratory volume at one second (FEV (1.0)) and FEV(1)/FVC ratio. The FVC and FEV(1.0) shall be obtained in a manner consistent with the most current American Thoracic Society guidelines for standardization of spirometry including acceptability and repeatability criteria.</p>	<p>(4) <u>Content of examination.</u> A medical examination consists of, at a minimum:</p> <p>(i) A medical and work history, with emphasis on past, present and potential exposure to flavorings containing diacetyl;</p> <p>(ii) A physical examination with emphasis on the respiratory system, eyes and the integumentary system;</p>
	<p>(4) <u>Equipment Standards.</u> All spirometry equipment used to meet the medical surveillance requirements of this section shall:</p>	<p>(iii) Completion of the respiratory questionnaire in Appendix or other equivalent questionnaire;</p>
	<p>(i) pass all laboratory standards for accuracy and precision criteria, using either the ATS 1994 spirometry evaluation protocol, or validation from an independent laboratory, if equipment is purchased after the effective date of this section; for equipment purchased prior to the effective date, the employer shall obtain information from the equipment vendor as to the extend that the equipment being used meets accuracy and precision criteria from either of the above sources;</p>	<p>(iv) Spirometry administered by individuals who have completed a training course in spirometry that is certified by NIOSH;</p>
	<p>(ii) be checked for calibration at least daily, when in use, following ATS guidelines;</p>	<p>(vi) any other additional tests deemed appropriate by the PLHCP; and</p>
		<p>(v) At a minimum, spirometry shall include measurement of forced vital capacity (FVC) and forced expiratory volume at one second (FEV (1.0)) and FEV(1)/FVC ratio. The FVC and FEV(1.0) shall be obtained in a manner consistent with the most current American Thoracic Society guidelines for standardization of</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>(iii) provide, at a minimum, tracings that meet the minimum size and resolution requirements set forth by ATS.</p> <p>(5) <u>Information provided to the PLHCP.</u> The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:</p> <p>(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to flavorings containing diacetyl;</p> <p>(ii) The employee's former, current, and anticipated levels of occupational exposure to flavorings containing diacetyl;</p> <p>(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and</p> <p>(iv) Records of employment-related medical examinations previously provided to the affected employee, including all previous spirometry measurements, currently within the control of the employer.</p> <p>(6) <u>PLHCP's written medical opinion.</u></p>	<p>spirometry including acceptability and repeatability criteria.</p> <p>(4) <u>Equipment Standards.</u> All spirometry equipment used to meet the medical surveillance requirements of this section shall:</p> <p>(i) Pass all laboratory standards for accuracy and precision criteria, using either the ATS 1994 spirometry evaluation protocol, or validation from an independent laboratory, if equipment is purchased after the effective date of this section; for equipment purchased prior to the effective date, the employer shall obtain information from the equipment vendor as to the extent that the equipment being used meets accuracy and precision criteria from either of the above sources;</p> <p>(ii) Be checked for calibration at least daily, when in use, following ATS guidelines;</p> <p>(iii) Provide, at a minimum, tracings that meet the minimum size and resolution requirements set forth by ATS.</p> <p>(5) <u>Information provided to the PLHCP.</u> The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:</p> <p>(i) A description of the affected employee's former, current, and anticipated duties as they relate to the</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>(i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:</p> <p>(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to flavorings containing diacetyl;</p> <p>(B) Any recommended limitations upon the employee's exposure to flavorings containing diacetyl, or upon the use of personal protective equipment such as respirators, and</p> <p>(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to flavorings containing diacetyl exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.</p> <p>(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to flavorings containing diacetyl.</p> <p>(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.</p>	<p>employee's occupational exposure to flavorings containing diacetyl;</p> <p>(ii) The employee's former, current, and anticipated levels of occupational exposure to flavorings containing diacetyl;</p> <p>(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and</p> <p>(iv) Records of employment-related medical examinations previously provided to the affected employee, including all previous spirometry measurements, currently within the control of the employer.</p> <p>(6) <u>PLHCP's written medical opinion.</u></p> <p>(i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:</p> <p>(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to flavorings containing diacetyl;</p> <p>(B) Any recommended limitations upon the employee's</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>(7) <u>Additional Testing and Referrals.</u></p> <p>(i) In the event of abnormal spirometry or other unusual findings associated with occupational exposure to flavorings containing diacetyl, the PLHCP shall refer the employee to a pulmonary specialist for a more complete evaluation within 14 days; and</p> <p>(ii) The employer shall provide and pay for any additional medical services recommended by the PLHCP or the pulmonary specialist.</p> <p>(iii) The employer shall ensure that the examining pulmonary specialist is provided with all the information that the employer is obligated to provide to the PLHCP.</p>	<p>exposure to flavorings containing diacetyl, or upon the use of personal protective equipment such as respirators; and</p> <p>(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to flavorings containing diacetyl exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.</p> <p>(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to food containing diacetyl.</p> <p>(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.</p> <p>(7) <u>Additional Testing and Referrals.</u></p> <p>(i) In the event of abnormal spirometry or other unusual findings associated with occupational exposure to flavorings containing diacetyl, the PLHCP shall refer the employee to a pulmonary specialist for a more complete evaluation within 14 days; and</p> <p>(ii) The employer shall provide and pay for any additional medical services recommended by the PLHCP or the pulmonary specialist.</p>
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

		(iii). The employer shall ensure that the examining pulmonary specialist is provided with all the information that the employer is obligated to provide to the PLHCP.
Housekeeping	<p>(1) All surfaces shall be maintained as free as practicable of accumulations of flavorings containing diacetyl.</p> <p>(2) The employer shall institute a program for detecting leaks and spills of flavorings containing diacetyl, as required under paragraph (1)(iv) of the exposure control plan provisions, including regular visual inspections of operations involving liquid or powder formulations of flavorings containing diacetyl.</p> <p>(3) All leaks shall be repaired and accumulations of liquid or powder shall be cleaned up promptly using methods that minimize the likelihood of exposure to flavorings containing diacetyl.</p> <p>(4) Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with flavorings containing diacetyl shall be collected and disposed of in a manner to prevent the re-entry of flavorings containing diacetyl into the workplace.</p>	(The Agency anticipates that provisions relating to housekeeping will be the same in PEL and non-PEL proposals)
Recordkeeping	(1) <u>Air monitoring</u> data. (i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.	(The Agency anticipates that provisions relating to recordkeeping will be the same in PEL and non-PEL proposals)

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(ii) This record shall include at least the following information:</p> <p>(A) The date of measurement for each sample taken;</p> <p>(B) The operation involving exposure to flavorings containing diacetyl that is being monitored;</p> <p>(C) Sampling and analytical methods used and evidence of their accuracy;</p> <p>(D) Number, duration, and the results of samples taken;</p> <p>(E) Type of personal protective equipment, such as respirators worn; and</p> <p>(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.</p> <p>(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.</p> <p>(2) <u>Historical monitoring data.</u></p> <p>(i) Where the employer has relied on historical monitoring data to determine exposure to flavorings containing diacetyl, the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.</p>	
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(ii) The record shall include information that reflects the following conditions:</p> <p>(A) The data were collected using methods that meet the accuracy requirements stated in the exposure assessment paragraph</p> <p>(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;</p> <p>(C) The characteristics of the material (containing flavorings containing diacetyl) being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;</p> <p>(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and</p> <p>(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.</p> <p>(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.</p>	
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(3) <u>Objective data.</u> (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.</p> <p>(ii) This record shall include at least the following information:</p> <p>(A) The material in question (flavorings containing diacetyl);</p> <p>(B) The source of the objective data;</p> <p>(C) The testing protocol and results of testing, or analysis of the material for the release of flavorings containing diacetyl;</p> <p>(D) A description of the process, operation, or activity and how the data support the determination; and</p> <p>(E) Other data relevant to the process, operation, activity, material, or employee exposures.</p> <p>(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.</p> <p>(4) <u>Medical surveillance.</u> (i) The employer shall establish and maintain an accurate record for each employee that is covered by the medical surveillance provisions of this section.</p>	
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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	<p>(ii) The record shall include the following information about the employee:</p> <p>(A) Name and social security number;</p> <p>(B) A copy of the PLHCP's written opinions;</p> <p>(C) A copy of the information that the employer is obligated to provide to the PLHCP under paragraph (6) of the medical surveillance provisions.</p> <p>(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.</p>	
Prohibited Practices	<p>(1) Compressed air, dry sweeping, or vacuuming unless the vacuum is equipped with a HEPA filter shall not be used to clean or remove flavorings containing diacetyl</p> <p>(2) Containers of flavorings containing diacetyl must not be left uncovered when not in use.</p> <p>(3) Wastewater or solvent used for cleaning equipment shall not be discharged onto the floor.</p>	<p>(The Agency anticipates that provisions relating to prohibited practices will be the same in PEL and Non-PEL proposals)</p>
Dates	<p>(1) Effective date. The standard shall become effective 30 days after publication in the Federal Register.</p> <p>(2) The following shall take effect on or before 60 days after the effective date:</p>	<p>(1) Effective date. The standard shall become effective 30 days after publication in the Federal Register.</p> <p>(2) The following shall take effect on or before 60 days after the effective date:</p>

Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

<p>(i) Exposure Assessment;</p> <p>(ii) Hazard Communication;</p> <p>(iii) Housekeeping;</p> <p>(iv) Prohibited Practices.</p> <p>(3) The following shall take effect on or before 90 days after the effective date:</p>	<p>(i) Exposure Control Plan;</p> <p>(ii) Exposure Assessment;</p> <p>(iii) Hazard Communication;</p> <p>(iv) Housekeeping</p> <p>(v) Prohibited Practices.</p> <p>(3) The following shall take effect on or before 90 days after the effective date:</p>
<p>(i) Respiratory Protection;</p> <p>(ii) Protective Work Clothing and Equipment;</p> <p>(iii) Regulated Areas;</p> <p>(iv) Medical Surveillance; and</p> <p>(v) Recordkeeping.</p>	<p>(i) Respiratory Protection;</p> <p>(ii) Protective Work Clothing and Equipment;</p> <p>(iii) Regulated Areas;</p> <p>(iv) Medical Surveillance; and</p> <p>(v) Recordkeeping.</p>
<p>(4) The Engineering Controls shall take effect on or before 2 years after the effective date.</p>	<p>(4) The Engineering Controls shall take effect on or before 2 years after the effective date.</p>